

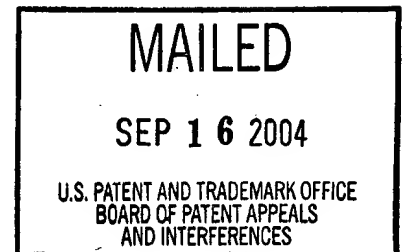
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JULIUS REBEK and KENT E. PRYOR

Appeal No. 2003-0866
Application No. 09/246,468

ON BRIEF



Before WILLIAM F. SMITH, SCHEINER and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1-15, the only claims remaining in the application.

Each of the claims is directed to a compound of Structure I, a derivative of a glycoluril. The claims are reproduced in Appendix A, which accompanied appellants' Brief on Appeal (paper no. 17).

No references are relied on by the examiner.

Claims 1-15 stand rejected under 35 U.S.C. § 101. According to the examiner, "the claimed invention is not supported by either a specific asserted utility or a well-established utility" (Answer, page 3). In addition, the claims stand rejected under the first paragraph of 35 U.S.C. § 112.

We reverse the examiner's rejections of the claims.

BACKGROUND

"Combinatorial chemistry, introduced for polypeptide and oligonucleotide libraries, has undergone a rapid development and acceptance . . . [W]hen applied to generating non-peptide small molecule diversity, [it] has provided a new paradigm for drug discovery. Perhaps as a consequence of the extension of the concept from peptide and oligonucleotide synthesis, the majority of applications have relied on solid-phase synthesis and methodological advances continue to extend common synthetic transformations to polymer-supported versions" (Specification, pages 2-3). "Solution phase synthesis has emerged as [another] method for [] generating combinatorial libraries . . . [and] is more rapid and efficient than . . . solid phase synthesis" (id., page 17). While "[s]olid phase synthesis typically yields only a few nanograms of product . . . [solution phase synthesis] yields milligrams and grams of product" (id.).

The recognition that "certain receptors and proteins appear to bind their ligands utilizing small clusters of residues for the majority of the binding interaction has led to the expectation that small molecules may be capable of triggering a receptor response . . . [D]etailed knowledge concerning the dimerization modes and ligand binding domains of single transmembrane domain receptors will provide a basis for the design of functional agonists as well as ligand antagonists. However, the noncontiguous and multiple binding domains involved in both the protein-protein and ligand-protein interactions make it difficult to assess the dimerization mode or ligand binding domains in the absence of three-dimensional structural information" (id., pages 1-2).

The claimed glycoluril compound of Structure I is described as "a core molecule for use in constructing a [soluble] combinatorial library" (id., page 4). According to

appellants, core molecules increase the three-dimensional structural diversity of prepared libraries (id., page 6) because different core molecules “provide different orientations of the attached [library] building blocks” (id., page 1). According to appellants, “[t]he properties of the core molecules have (in several assays) been critical to activity, as libraries made with the same building blocks and linkages have had very different activity levels” (id., page 1).

DISCUSSION

Utility

Claims 1-15 stand rejected under 35 U.S.C. § 101 as lacking utility (Answer, page 3). As framed by the examiner, “the issue . . . is whether the fact that the claimed compounds can be used to create combinatorial libraries that can be screened, without more, constitutes an ‘immediate benefit to the public’” (id., page 4). Skipping right over the claimed compounds, the examiner argues: “[h]ad the specification taught that any of the [resultant library] compounds had a useful activity, then those compounds would be of immediate benefit to the public [and] [t]he other compounds would then enjoy a rebuttable presumption that they also possess the specified activity. The burden would then be on the USPTO to assert, by a preponderance of the evidence , that the proposed utility is not credible” (Footnote 1, page 5).

In our view, this is putting the cart before the horse. The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (“Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.”).

According to the specification, and not disputed by the examiner, the claimed compounds can be used as soluble supports for solution phase combinatorial chemistry. Further according to the specification, and not disputed by the examiner, combinatorial libraries made with the same building blocks, but different core compounds, can have different three-dimensional repertoires, and therefore, different ranges of activity. The examiner has not begun to explain why the asserted utility of the claimed compounds (that of providing a soluble support for a combinatorial library and dictating, at least in part, its three-dimensional repertoire), is not of "immediate benefit to the public." That is, the examiner has not explained why the claimed compounds, in and of themselves, lack utility as soluble, three-dimensional supports, or why one skilled in the art would doubt the asserted utility.

On this record, we see no justification for shifting the burden of establishing utility to appellants. The rejection of claims 1-15 under 35 U.S.C. § 101 is reversed.

Enablement

Claims 1-15 also stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement since "one skilled in the art clearly would not know how to use the claimed invention" in the absence of a specifically asserted or well established utility (Answer, page 8).

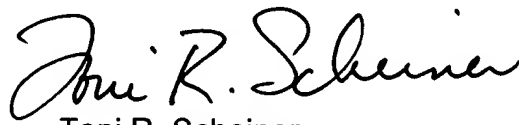
This rejection is untenable on its face. The specification explicitly teaches how to use the claimed compounds as supports for soluble combinatorial libraries (see, e.g., pages 17-18 of the specification). The rejection of claims 1-15 under 35 U.S.C. § 112, first paragraph, is reversed

CONCLUSION

In our opinion, the examiner's initial burden of establishing lack of utility or lack of enablement has not been met. The rejections of claims 1-15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, are reversed.

REVERSED


William F. Smith
Administrative Patent Judge


Toni R. Scheiner
Administrative Patent Judge

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Eric Grimes
Administrative Patent Judge

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